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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,214	09/21/2005	Ivan Salgo	US030075	9554

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EXAMINER	
CARTER, AARON W	
ART UNIT	**PAPER NUMBER**
2624	

MAIL DATE	DELIVERY MODE
02/25/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/550,214	SALGO ET AL.	
	Examiner	Art Unit	
	AARON W. CARTER	2624	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 November 2008*.

2a)☐ This action is FINAL. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,10 and 14-19* is/are rejected.

7)☒ Claim(s) *6-9 and 11-13* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 September 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This action is responsive to papers filed on 11/20/08.

Response to Amendment

2. In response to applicant's amendment received on 11/20/08, all requested changes to the claims have been entered.

Response to Arguments

3. Applicant's arguments, see Remarks, filed 11/20/08, with respect to the rejection(s) of claim(s) 1, 14 and 15 under 35 USC 102(e) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of USPN 6,996,430 to Gilboa et al.

Specification

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.

(d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
(e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
(f) BACKGROUND OF THE INVENTION.
(1) Field of the Invention.
(2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(g) BRIEF SUMMARY OF THE INVENTION.
(h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(i) DETAILED DESCRIPTION OF THE INVENTION.
(j) CLAIM OR CLAIMS (commencing on a separate sheet).
(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
(l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

4. The disclosure is objected to because of the following informalities:

The specification lack section headings.

Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. The significant step of "merging information..." could not be performed manually and therefore inherently requires the use of a computer or a processor. Therefore, claim is tied to a particular machine and thus eligible under 35 U.S.C. 101.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-5 and 14-17 are rejected under 35 U.S.C. 102(e) as being anticipated by USPN 6,996,430 to Gilboa et al. ("Gilboa").

As to claim 1, Gilboa discloses a method of observing the operation of an invasive medical device comprising:

Operating an invasive medical device from an invasive medical device system to perform an activity within a body (*Fig. 1, element 170 and column 7, line 51 - column 8, line 17*);

Operating an ultrasonic diagnostic imaging system to observe the invasive medical device by means of a real time three dimensional ultrasonic image (*column 10, lines 47-56*);

Producing information with the invasive medical device system having coordinate information relating to the activity (*column 9, lines 17-20 and column 10, lines 14-17*); and

Merging information from the invasive medical device system into the real time three dimensional ultrasonic image at a location in the ultrasonic image data which is determined from the coordinate information (*column 10, lines 14-17*).

As to claim 2, Gilboa discloses the method of claim 1, wherein the invasive medical device includes a position sensor; and

Wherein producing information with the invasive medical device system comprises producing coordinate information in response to signals received from the position sensor (*Fig. 1, element 138 and column 9, lines 17-20*).

As to claim 3, Gilboa discloses the method of claim 2, wherein the position sensor comprises a receiver which receives signals in an acoustic, optical radio frequency, or electromagnetic spectrum (*column 8, lines 56-67*).

As to claim 4, Gilboa discloses the method of claim 2, wherein the position sensor comprises a transmitter which transmit signals in the acoustic, optical, radio frequency or electromagnetic spectrum (*column 8, lines 56-67*).

As to claim 5, Gilboa discloses the method of claim 1, wherein merging information further comprises merging locational information into the real time three dimensional ultrasonic image at locations where activity of the invasive medical device has been performed (*column 10, lines 14-17*).

As to claim 14, Gilboa discloses a method of guiding the placement of an invasive medical device with a three dimensional ultrasonic imaging and invasive medical device operating system comprising:

Operating an invasive medical device by means of an interventional device subsystem to perform an activity within a body (*Fig. 1, element 170 and column 7, line 51 - column 8, line 17*);

Acquiring ultrasonic echo information by means of an ultrasonic imaging subsystem from a volumetric region containing the invasive medical device (*column 10, lines 47-56*);

Producing information from the invasive medical device having coordinate information relating to the activity (*column 9, lines 17-20 and column 10, lines 14-17*);

Producing a real time three dimensional ultrasonic image with spatially coordinated invasive medical device activity information from the ultrasonic echo information and the information from the invasive medical device (*column 10, lines 14-17*); and

Displaying the real time three dimensional ultrasonic image with spatially coordinated invasive medical device activity information on an image display (*column 10, lines 14-17*).

As to claim 15, Gilboa discloses an ultrasonic surgical guidance imaging system which acts to observe the operation of an invasive medical device comprising:

An ultrasonic probe including an array transducer which steers ultrasonic beams over a volumetric region for image guidance of the operation of an invasive medical device (*Fig. 1, element 120 and column 10, lines 47-56*);

An ultrasound acquisition subsystem coupled to the ultrasonic probe (*Fig. 1, element 125 and column 10, lines 47-56*);

An invasive medical device (*Fig. 1, element 170*);

An interventional device subsystem coupled to the invasive medical device (*Fig. 1, element 130*);

A 3D image processor coupled to the ultrasound acquisition subsystem and the interventional device subsystem which operates to produce 3D ultrasound images containing locational information of the invasive medical device in real time (*Fig. 1, element 140 and column 10, lines 14-17*); and

An image display coupled to the 3D image processor (*Fig. 1, elements 160 and 162*).

As to claim 16, Gilboa discloses the ultrasonic surgical guidance imaging system of claim 15, wherein the invasive medical device further includes a position sensor (*Fig. 1, element 138*); and wherein the interventional device subsystem further includes a device position measurement subsystem coupled to the position sensor (*Fig. 1, element 130*).

As to claim 17, Gilboa discloses the ultrasonic surgical guidance imaging system of claim 16, wherein the 3D image processor is further responsive to locational signals produced by the device position measurement subsystem (*Fig. 1, element 140 and column 10, lines 14-17*).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claim 10, 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gilboa in view of USPN 2002/0049375 of Strommer et al. ("Strommer") (already of record).

As to claim 10, Gilboa discloses the method of claim 1.

Gilboa does not disclose expressly acquiring ECG data; and further comprising displaying both the real time three dimensional ultrasonic image containing merged information from the invasive medical device system and an ECG trace.

However, Strommer discloses displaying both the real time ultrasonic image containing merged information from the invasive medical device system and an ECG trace (*Fig. 1, paragraphs 41, 116, 117, 167*).

Gilboa & Strommer are combinable because they are from the same art of image processing.

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the process of displaying both a real time ultrasonic image and ECG trace, as taught by Strommer, with the method of observing the operation of an invasive medical device disclosed by Gilboa.

The suggestion/motivation for doing so would have been to provide a graphical user interface comprising image data as well ECG data that can be monitored which enhances diagnostics (*Strommer, paragraph 3 and 41*).

Therefore, it would have been obvious to combine Gilboa with Strommer to obtain the invention as specified in claim 10.

As to claim 18, please refer to the rejection of claim 10 above.

As to claim 19, please refer to the rejection of claim 10 above.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claim 1 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/550212.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the limitations of claim 1 in the present application can be found in an obvious variation in the limitations of claim 1 in Application 10/550212.

As to claim 1, 10/550212 discloses a method of observing the operation of an invasive medical device (*claim 1, lines 1-3*) comprising:

Operating an invasive medical device from an invasive medical device system to perform an activity within a body (*claim 1, lines 1-3*);

Operating an ultrasonic diagnostic imaging system to observe the invasive medical device by means of a real time three dimensional ultrasonic image (*claim 1, lines 4-6*);

Producing information with the invasive medical device system having coordinate information relating to the activity (*claim 1, lines 11-12*); and

Merging information from the invasive medical device system into the real time three dimensional ultrasonic image at a location in the ultrasonic image data which is determined from the coordinate information (*claim 1, lines 13-16*).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Allowable Subject Matter

9. Claims 6-9 and 11-13 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 2002/0072674 to Criton et al. discloses ultrasonic image processing.

US 20030158477 to Panescu discloses ultrasonic image processing.

USPN 6,606,089 to Margadant discloses ultrasonic image processing.

USPN 6,379,302 to Kessman et al. discloses ultrasonic image processing.

US 2003/0060700 to Solf et al. discloses ultrasonic image processing.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARON W. CARTER whose telephone number is (571)272-7445. The examiner can normally be reached on 8am - 4:30 am (Mon. - Fri.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Werner can be reached on (571) 272-7401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Aaron W Carter/
Primary Examiner, Art Unit 2624